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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,323	01/18/2002	De-Chu C. Tang	858610-2003.2	3301
20999	7590	12/15/2004	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			WOITACH, JOSEPH T	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/052,323

Applicant(s)

TANG ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-18,20-26,28-32 and 35-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-18,20-26,28-32 and 35-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This application filed January 18, 2002 is a continuation in part of 09/563,826, filed May 3, 2000, now US Patent 6,348,450, which claims benefit to 60/132,216 filed May 3, 1999; and is a continuation in part of 09/533,149, filed March 23, 2000, now US Patent 6,716,823, which is a continuation in part of 09/402,527, filed January 3, 2000, now US Patent 6,706,693, which is a 371 national stage entry of PCT/US98/16739 filed August 13, 1998, which claims benefit to provisional applications 60/055,520, filed August 13, 1997 and 60/075,113, filed February 11, 1998.

Applicants' amendment filed August 18, 2003 has been received and entered. Claims 2, 5, 18, 19, 27, 33, 34 have been canceled. Claim 40 has been added. Claims 1, 3, 4, 6-17, 20-26, 28-32 and 35-40 are pending.

### ***Election/Restriction***

Applicant's election with traverse of Group I in the reply filed on August 18, 2003 is acknowledged. The traversal is on the ground(s) that the inventions are not distinct and would not constitute an undue burden for examination of both groups. This is found persuasive in part because while the inventions could be considered distinct because of their difference in outcome, examiner would agree that it would not constitute an undue burden to examine both groups together.

With respect to the election of species, Applicants have elected the species of *Escherichia* with traverse. The traversal is on the ground(s) that it would not be an undue burden to examine

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the genus and all the species because the species are related to the extent they are used in the same methods. Further, it is argued that because each of the species does not have a separate classification the search would be co-extensive and thus, the Examiner has not sufficiently demonstrated a search burden. This is not found persuasive because

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 3, 4, 6-17, 20-26, 28-32 and 35-40 are pending. Claims 3, 7, 8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species of the invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement. Claims 1, 4, 6, 9-17, 20-26, 28-32 and 35-40, drawn to a method of non-invasive immunization or induction of systemic immune response to a gene product in an animal comprising contacting the skin of said animal with the species of bacterium *Escherichia* that comprises and expresses the gene product.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information

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submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Specifically, on pages 54-55, the specification provides a list of reference however it is unclear if all are provided in an IDS. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Priority***

This application repeats a substantial portion of 09/563,826, filed May 3, 2000, now US Patent 6,348,450, which claims benefit to 60/132,216 filed May 3, 1999 and 09/533,149 filed March 23, 2000, now US Patent 6,716,823, and adds and claims additional disclosure not presented in the prior applications. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application.

Review of the priority documents indicates that that elected invention a method of non-invasive immunization or induction of systemic immune response to a gene product in an animal comprising contacting the skin of said animal with a bacterium is first present in the instant application. Since support for the claimed invention is found first in the instant application, it has been given the priority date as of its filing January 18, 2002.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 6 is indefinite in the recitation of an "epitope of interest" because 'interest' is a subjective term subjective to various interpretations. The metes and bounds of the claims can not be defined by this terminology.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 6, 9-17, 20-26, 28-32 and 35-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 10/346,021. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods recite and encompass the same subject matter (see claim 1 with the recitation of 'bacterium'), and dependent claims specifically recite the elected species (see for example claims 2, 5 and 6).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.



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Claims 1, 4, 6, 9-17, 20-26, 28-32 and 35-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 10/116,963. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods recite and encompass the same subject matter (see claim 1 with the recitation of "bacterial vectors"), and dependent claims specifically recite the elected species (see for example claims 2 and 3).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 6, 9-17, 20-26, 28-32 and 35-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Krieg *et al.* (US Patent 6,339,068 B1-IDS reference).

Claim 1 as it is drawn to the elected invention encompasses a method of induction of systemic immune response to a gene product in an animal comprising contacting the skin of said animal with a bacterial vector that comprises and expresses the gene product. Dependent claims set forth specific antigens and animals in which the method is practiced. Krieg *et al.* teach vectors and methods for immunization. The vaccines described by Krieg *et al.* primarily focus

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on the ability of CpG sequences to enhance the immune response. Krieg *et al.* provide a variety of vectors for practice of the method including the bacteria from which the CpG sequence was first characterized and derived. Krieg *et al.* include the delivery and expression of any gene of interest and includes an extensive list of viral, bacterial and possible cancer antigens as antigens of interest. Additional, it is taught that immunomodulatory sequences can be introduced and expressed to enhance the immune response. Finally, Krieg *et al.* provide a variety of routes of administration known in the art, including the use of a gene gun for the delivery of a vaccine to the skin.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Steidler *et al.* Infect and Imm 66(7):3183-3189, July 1998.

Chen *et al.* Infect and Imm 55(10):2534-2537, October 1987.

Each reference provides evidence that live and attenuated bacteria can be used for immunization. Each provide methods for different types of immunization in a model system and different routes of administration, however neither of the references, nor the art of record indicate that bacterium can cross the barrier of the skin and result in a systemic immune response as instantly claimed.

### ***Conclusion***

No claim is allowed.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

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